



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
-----------------	-------------	----------------------	---------------------	------------------

10/775,366

02/10/2004

David Hung

12.016011-CON

1188

38732

7590

07/11/2008

CYTYC CORPORATION

250 CAMPUS DRIVE

MARLBOROUGH, MA 01752

EXAMINER

KIM, JENNIFER M

ART UNIT

PAPER NUMBER

1617

MAIL DATE

DELIVERY MODE

07/11/2008

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/775,366	Applicant(s) HUNG ET AL.	
	Examiner Jennifer Kim	Art Unit 1617	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 15 April 2008.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 2-5 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 2-5 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

The response filed April 8, 2008 have been received and entered into the application.

Action Summary

The rejection of claims 3 and 4 under 35 U.S.C. 103(a) as being unpatentable over Tabar et al. is being maintained for the reasons stated in the previous Office Action.

The rejection of claims 2 and 5 under 35 U.S.C. 103(a) as being unpatentable over Tabar et al. in view of Stamler et al. (U.S. Patent No. 5,380,758) is being maintained for the reasons stated in the previous Office Action.

Response to Arguments

Applicants' arguments filed April 15, 2008 have been fully considered but they are not persuasive. Applicants argue that there is no teaching or suggestion in Tabar et al. of the use of an anesthetic and certainly no description of the use of an anesthetic for the facilitation of the collection of ductal fluid. This is not found to be persuasive because Tabar et al. teach that the galactography is a painful procedure and that gently

Art Unit: 1617

inserting the blunt needle or cannula into the secreting duct is most difficult. This teaching would motivated on of ordinary skill in the art to coat the tip of ductal access tool with an anesthetic agent in order to avoid the painful process upon direct contact of blunt needle causing pain during the procedure. Applicants argue that there is simply no teaching or suggestion in Tabar et al. or in Stamler et al. of the use of anesthetic or a muscle relaxing agent for the facilitation of the collection of ductal fluid and the obviousness rejection is based on hindsight from these disparate references to provide random element of the claims. This is not persuasive because it must be recognized that any judgment on obviousness is in a sense necessarily a reconstruction based upon hindsight reasoning. But so long as it takes into account only knowledge which was within the level of ordinary skill at the time the claimed invention was made, and does not include knowledge gleaned only from the applicant's disclosure, such a reconstruction is proper. See *In re McLaughlin*, 443 F.2d 1392, 170 USPQ 209 (CCPA 1971). In this case, the claimed invention, as a whole, would have been obvious to one of ordinary skill in the art at the time the invention was made, because every element of the invention and the particular problem with which the applicants were concerned have been collectively taught by the combined teachings of the references. It is noted that Tabar et al. teach an intraductal injection comprising employment of ductal access tool (a standard needle) comprising methylene blue dye and contrast material with recognized difficult steps involving painful contact with a blunt tip of the needle, and Stamler et al. teach that muscle relaxing agent alleviates smooth muscle contraction spasm and facilitates procedure involving fluid aspiration. Therefore, it would have

Art Unit: 1617

been obvious to one of ordinary skill in the art to modify the method of Tabar et al. and incorporate an anesthetic agent and a muscle relaxing agent to the intraductal injection of Tabar et al. in order to ease the pain and facilitate the most difficult step of insertion of the blunt needle into the duct. Thus, the claims fail to patentably distinguish over the state of the art as represented by the cited references.

Claim Rejections - 35 USC § 103

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 3 and 4 are rejected under 35 U.S.C. 103(a) as being unpatentable over Tabar et al.

Tabar et al. on the abstract and page 31 right-hand column, teach an intraductal injection comprising a standard needle (ductal access tool) comprising methylene blue dye and contrast material. Tabar teach that the most difficult step in galactography is gently inserting the blunt needle or cannula into the secreting duct. (page 31, right-hand column) and the procedure is painful. (page 36 middle column).

Tabar et al. do not expressly teach coating tip of a ductal access tool with anesthetic agent.

It would have been obvious to one of ordinary skill in the art to modify the teaching of Tabar et al. and coat the tip of a ductal access tool with an anesthetic agent because the most difficult step in accessing breast duct in galactography is inserting the blunt needle or cannula into the secreting duct and the procedure is very painful as taught by Tabar et al. One would have been motivated to make such a modification in order to achieve an expected benefit to numb the affected breast duct to be treated in order to ease the most difficult step in galactography. There is a reasonable expectation of successfully facilitating ductal access by coating the tip of ductal access tool by an anesthetic agent because the procedure of inserting blunt needle or cannula into the secreting duct is painful and the most difficult step in view of Tabar et al.

Claims 2 and 5 are rejected under 35 U.S.C. 103(a) as being unpatentable over Tabar et al. in view of Stamler et al. (U.S. Patent No. 5,380,758).

Tabar et al. on the abstract and page 31 right-hand column, teach an intraductal injection comprising a standard needle (ductal access tool) comprising methylene blue dye and contrast material. Tabar et al. teach that the most difficult step in galactography is gently inserting the blunt needle or cannula into the secreting duct. (page 31, right-hand column) and the procedure is painful. (page 36 middle column).

Tabar et al. do not teach fluid collection comprising a muscle-relaxing agent and an anesthetic agent to facilitate ductal access or ductal fluid collection or both.

Stamler et al. teach S-nitrosothiol alleviates smooth muscle contraction and spasm and facilitates procedures involving diagnostic instrumentation such as

Art Unit: 1617

endoscope including fluid aspiration. (abstract, column 9, lines 55-62, column 22, claim 23).

It would have been obvious to one of ordinary skill in the art to modify the method of Tabar et al. and incorporate an anesthetic agent and a muscle relaxing agent to the intraductal injection of Tabar et al. because an anesthetic agent is needed in galactography in intraductal fluid because the procedure is painful and it is difficult to insert the blunt needle into the secreting duct procedure in view of Tabar et al. Moreover, a muscle relaxing agent is useful in fluid aspiration procedure because it facilitates and alleviates any muscle contraction or spasm. One would have been motivated to combine an anesthetic and a muscle relaxing agent in an intraductal injection in order to numb the pain and facilitates the procedure involving fluid aspiration in galactography. Thus, the claims fail to patentably distinguish over the state of the art as represented by the cited references.

None of the claims are allowed.

THIS ACTION IS MADE FINAL. Applicants are reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jennifer Kim whose telephone number is 571-272-0628. The examiner can normally be reached on Monday through Friday 6:30 am to 3 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreenivasan Padmanabhan can be reached on 571-272-0629. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR.

Art Unit: 1617

Status information for unpublished applications is available through Private PAIR only.

For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Jennifer Kim/
Primary Examiner, Art Unit 1617

Jmk
July 3, 2008